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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,892	10/01/2007	Christian Hansen	11591-008-999 (CAM: 78200	3750
20583	7590	05/25/2010	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SOROUSH, ALI	
			ART UNIT	PAPER NUMBER
			1616	
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			05/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,892	Applicant(s) HANSEN ET AL.	
	Examiner ALI SOROUGH	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10262007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 contains the trademarks/trade names Sustiva, Retrovir, Epivir, Ziagen, Hivid, Videx, Zerit, Viread, Emtriva, Lexiva, Viramune, Rescriptor, Fuzeon, Invirase, Fortovase, Norvir, Crixivan, Reyataz, Viracept, and Agenerase. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe anti-retoviral compounds and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al. (International Application Published Under the PCT WO 02/062351 A1, Published 08/15/2002) in view of Marie et al. (Mechanism of Action and Therapeutic Potential of Strontium in Bone, Published 08/08/2001).

Applicant Claims

A method of treating an osteonecrotic bone in disease comprising administering an effective dose of strontium-containing compound.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Little et al. teach the treatment and prevention of osteonecrosis by the administration of bisphosphonate. (See title and abstract). "Application of therapeutically effective amount of bisphosphonate will slow the resorption and collapse of the necrotic bone, limit the resorption of the metaphyseal bone and promote increased mineral content in the new bone forming in the lateral portion of the epiphysis. By preventing collapse of the necrotic bone and increasing the mechanical integrity of the new bone, a more spherical shape of the femoral head will be maintained." (See page 15, Lines 202-

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25). Little et al. teach that osteonecrosis can result from exposure to glucocorticoids or cytotoxic drugs. (See page 1, Lines 11-20).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Little et al. lacks a teaching wherein the composition comprises a strontium-containing compound. This deficiency is cured by the teachings of Marie et al.

Marie et al. teach that strontium compounds specifically strontium ranelate increases bone formation and reduces bone resorption, leading to increased bone mass and improved bone mechanical properties. (See title and page 127, column 2, Lines 1-13).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Little et al. with Marie et al. One would have been motivated to do so because both Little et al. and Marie et al. are directed to treatment of bone conditions associated with loss of bone mass and mechanical properties. Furthermore, Little et al. and Marie et al. teach that both bisphosphonate and strontium ranelate act by increasing bone formation and reducing bone resorption. Therefore, it would have been obvious one ordinary skill in the art that strontium ranelate would also be useful in the treatment of osteonecrosis. For the foregoing reasons, the instant method would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616